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7590 01/22/2007 Bioarray Solutions			EXAMINER	
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SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Application No. Applicant(s)					
10/776,711 SHAH, MRUGESH	SHAH, MRUGESH				
Office Action Summary Examiner Art Unit	<u> </u>				
Mark Staples 1637					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)⊠ Responsive to communication(s) filed on <u>11/30/2006</u> .					
2a) ☐ This action is FINAL . 2b) ☑ This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the m	nerits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4)⊠ Claim(s) <u>1,3,9 and 11-16</u> is/are pending in the application.					
4a) Of the above claim(s) <u>2</u> , <u>4-8</u> , <u>and 10</u> is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1,3,9 and 11-16</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers					
9)⊠ The specification is objected to by the Examiner.					
10)⊠ The drawing(s) filed on <u>12/12/2004</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).	•				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:					
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)					
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application					
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application 6) Other:					

DETAILED ACTION

Election/Restrictions

1. Applicant's election of claims 1, 3, 9, and 11-16 of Group I in the reply filed on 11/29/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The cancellation of claims 2, 4-8, and 10 in the Claim Listing filed on 11/30/2006 is also acknowledged.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should reflect the

methods which are elected and references to non-elected inventions should be removed.

4. The abstract of the disclosure is objected to because of use of legal phraseology including the word "wherein". The abstract should also should be revised to eliminate those portions which are to non-elected inventions. Correction is required. See MPEP § 608.01(b).

Claim Objections

- 5. Claim 3 is objected to because of the following informalities: "Thoibacillu thoioparus" is a misspelling. Appropriate correction is required.
- 6. Claim 3 is objected to because of the following informalities: "aquaesullis" is a misspelling, there is only one "I". Appropriate correction is required.
- 7. Claim 12 is objected to because of the following informalities: recitation of "starting fossil fuel". It appears that the word "starting" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1637

Claims 1, 3, 9, and 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: converting solid fuels. It is noted that converting is given in the preamble of claim 1 but no step is given describing this conversion, especially how it is to be accomplished. It is also unclear how the microorganisms of these claims relate to the conversion as no active step is given in which the microorganisms interact with the solid fuels.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: improving converting solid fuels. It is noted that converting is given in the preamble of claim 9 but no step is given describing this conversion improvement, especially how it is to be accomplished. It is also unclear how the microorganisms of these claims relate to the improved conversion as no active step is given in which the microorganisms interact with the solid fuels.

Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: converting carbon, hydrogen and oxygen into fossil fuels. It is noted that converting is given in the preamble of claim 11 but no step is given describing this conversion, how it is to be accomplished. It is also

unclear how the microorganisms of these claims relate to the conversion as no active step is given in which the microorganisms interact with carbon, hydrogen, and oxygen.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). In claims 1 and 9 contemporary substances of turf, grass, glucose, rubber and wood are distilled in the present to yield coal or oil tars which are described as "fossil fuels" (*emphasis* by Examiner). In claim 11 carbon, hydrogen and oxygen are converted into "fossil fuels" in the present, not the past. The term fossil fuel is indefinite because the specification does not clearly redefine the term.

For reference, the following is an accepted definition of fossil fuel:

"fossil fuel

NOUN: A hydrocarbon deposit, such as petroleum, coal, or natural gas, derived from living matter of a previous geologic time and used for fuel"

The American Heritage® Dictionary of the English Language: Fourth Edition.

2000.

Available online at:

http://www.bartleby.com/61/61/F0276100.html

Art Unit: 1637

Where applicant acts as his or her own lexicographer to specifically define a term

Page 6

of a claim contrary to its ordinary meaning, the written description must clearly redefine

the claim term and set forth the uncommon definition so as to put one reasonably skilled

in the art on notice that the applicant intended to so redefine that claim term. Process

Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed.

Cir. 1999). In claims 1, 9, and 11 petroleum is produced through an engineered

process (gene transfection) which is not the accepted meaning of this word.

For reference, the following is an accepted definition of petroleum:

"petroleum

SYLLABICATION: pe-tro-le-um

NOUN: A thick, flammable, yellow-to-black mixture of gaseous, liquid, and solid

hydrocarbons that occurs naturally beneath the earth's surface, can be separated

into fractions including natural gas, gasoline, naphtha, kerosene, fuel and

lubricating oils, paraffin wax, and asphalt and is used as raw material for a wide

variety of derivative products."

The American Heritage® Dictionary of the English Language: Fourth Edition.

2000.

Available online at:

http://www.bartleby.com/61/61/F0276100.html

Claims 1, 3, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by "converting of solid fuels, including coal . . . by distillation of coal . . . ". It is unclear how coal can be obtained from coal by distillation of itself. A distinct recitation of the above elements and what may be intended in this claim can be found in lines 6 and 7 on page 1 of the specification. Substitution of the distinct recitation will overcome this rejection.

Claim 12 recites the limitation "production environment" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "nutrient" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 is indefinite for reciting "more production per unit nutrient or starting fossil fuel or oil tar" as both the fossil fuel and oil tar are not contributing to production, they are the things being produced. The following or similar wording may be intended: "more production *of* fossil fuel or oil tar per unit nutrient".

Regarding claims 1, 9, and 11, the phrase "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The terms "rocky", "sandy", "sand/water", "heat", "cold", "acidic", and "basic" in claim 13 are relative terms which renders the claim indefinite. The terms "rocky", "sandy", "sand/water", "heat", "cold", "acidic", and "basic" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and

one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The conditions under which the microorganisms can exist are thus rendered indefinite.

Claim 16 is incomplete because it depends from itself.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 9, and 11-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404.

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Art Unit: 1637

Claims 1, 3, 9, and 11-16 are broadly drawn to methods of producing product resembling the varied and complex fossil fuels and the multiple components of petroleum.

The unpredictability of the art and the state of the prior art

There is a great deal of unpredictability in field of biofuel production. Ethanol production has received a lot of attention owing to the availability of renewable feedstock from biomass. This technology is directed to production of just one compound, ethanol. Yet there is considerable difficulty in making ethanol production a viable process. The state of the art at the time of the claimed invention is revealed by Zaldivar et al. (2001):

"However, keeping a realistic perspective is important.

The improvement achieved in the fermentation step with the help of metabolic engineering is just one of the aspects of an integrated process. Hence, several pieces still remain to be properly assembled (and optimized) before an efficient industrial configuration is acquired. It is therefore anticipated that once in operation, the current model technologies will need several cycles of improvement/ analysis, before optimization and competitiveness are achieved" (see last paragraph on p. 30).

The post filing date art further confirms the unpredictability of this area. Jeffries et al. (2004) convey: "However, the bioconversion of pentoses to ethanol still

presents a considerable economic and technical challenge " (see 3rd sentence on p. 496). Lin et al. (2006) disclose: "In this field, although bioethanol production has been greatly improved by new technologies, there are still challenges that need further investigations. A further understanding of the ethanol fermentation needs to be reached" (see 2nd column, 1st paragraph, last 2 sentences on p. 627). And: "Recently, research has concentrated on the development of improved processes; however, there are still challenges that need further investigations" (see 2nd sentence under the section *Most promising prospects* on p. 635).

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied to apply this technology, including vairability of the fossil fuels such as coal from source to source, ability of the host microorganism to adapt and convert these varies sources to products found in petroleum, ability of the host microorganism to produce the multitude of compounds claimed, and the conditions necessary for the microorganism to produce those compounds. The time table necessary to achieve efficacious investigation of these parameters would require a very large quantity of experimentation. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Working Examples

The specification has no working examples of the claimed invention.

Guidance in the Specification.

The specification provides no evidence that a transfected host microorganisms would be able to produce the products found in fossil fuels including petroleum. The specification does not provide support that a host microorganism would be able to produce such products and produce more of them than the starting microorganism. As found in Table 1 of Ishizaki et al. (2001), the recombinant E. coli producing P(3HB) is not superior to two starting microorganisms P. extroquens and R. eutropha. Furthermore, Choi et al. (1998) show that several recombinant E. coli did not adequately generate product, as shown in Figure 3. Thus just making a transfected host microorganism does not guarantee it will adequately produce the products as claimed. The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to use the claimed invention. The specification merely discloses that one follow the complex procedure of gene identification and transfection followed by even the more complex procedure of selecting and optimizing growth conditions of the host microorganism to produce a vast arrays of distinct products by one cultivation of the host microorganism. Furthermore, the specification provides inadequate guidance to identify how many of the genes of the starting organism would need to be transfected. The products claimed to be produced are chemically more complex than ethanol and the expectation of the state of the art is that a complex metabolic pathway with several enzymes (and hence several genes of the starting microorganism) would be needed to yield the complex mixture of complex products. Thorough review of the prior art fails to show any enabled teachings of a transfected microorganism producing the multitude of products found in fossil fuels and petroleum.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, the factor of unpredictability weighs heavily in favor of undue experimentation in this highly unpredictable art where the variables of transfection of genes into mircoorganims to produce fuel depend upon numerous parameters such as what panel of genes may be needed, how the feedstack to be converted into fuel is to be pretreated, how the transfected microorganism is to be introduced into the feedstock and how its growth is to be maintained, and what the acceptable limits are of temperature, pressure, aeration or lack of aeration, and degree of mixing. Further, the prior art and the specification provides insufficient guidance to overcome the art recognized problems in the use of producing the complete range of products found in petroleum by genes from one specie of starting microorganism. Thus given the broad claims in an art whose nature is identified as unpredictable, the large quantity of research required to define the unpredictable variables, the lack of guidance provided in the specification, the absence of a working example, and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Due to the rejections noted above, the claims have been interpreted as follows in order to determine whether prior art is applicable.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi et al. (1998).

Regarding claim 11, Choi et al. (1998) teach a method of converting carbon, hydrogen and oxygen (as evidenced by Ishizaki et al. 2001 in the Abstract; who reference Choi et al. 1999 in Table 1; who in turn reference Choi et al. 1998 in the 1st paragraph on page 4364) into the polyhydroxyalkanoate (PHA) fuel which is poly (3-hydrozybutyrate); see Abstract of Choi et al. 1998. Choi et al. (1998) teach this method comprising:

isolating a starting microorganism capable of said conversion (entire reference especially the Abstract for *Alcaligenes latus* as the starting organism); isolating from the starting microorganism the genes responsible for the conversion ability;

transfecting the genes into a host microorganism (for these last 2 steps where the host organism is *E. coli*, see entire reference, especially the *Results* section beginning on page 4898 through to page 4900).

That poly(3-hydrozybutyrate) is combustable and hence is a fuel; as evidenced by Patel et al. in the last sentence on page 21: "Hence, if combusted in a waste incinerator . . . both plastics [PHA and PE] result in comparable CO₂ emissions throughout the life cycle".

Regarding claim 12, Choi et al. (1998) teach a method wherein, after transfection, the host microorganism is capable of more production per unit nutrient of fuel, than is the starting microorganism (see the three paragraphs on p. 4902 and as evidenced by Patel et al. in Table 3 where the Recombinant host *E. coli* of Choi et al. 1998 yields the most PHA of the listed organisms, including the starting microorganism, *A. latus*).

Regarding claim 13, Choi et al. (1998) teach a method wherein the host microorganism:

can exist in fresh water and can metabolize nutrient media (see p. 4364 for MR medium under the section *Culture Conditions*),

can survive an acidic environment (see p. 4364 for the acidic pH of 6.9 in the section Culture Conditions), or

can exist in aerobic conditions (see p. 4364 for oxygen concentration of 1 to 3% of air saturation in the section *Culture Conditions*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Page 15

11. Claims 1, 3, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurashov et al. (Patent No. RU 2,180,919 published in 2001, translated into English by the USPTO in December 2006) and Carroll et al. (1993).

Regarding claims 1, 3, and 9, Kurashov et al. teach a microbiological method of acting on solid fossil fuels including humites, anthracite, bituminous coal, and peat in any combinations with microorganisms, such as naturally occurring bacteria *Thiobacillus aquaesulis, Thiobacillus denitrificans, Thiosphaera pantropha,* or *Thiobacillus thioparus* to produce hydrocarbons identical to those contained in petroleum of natural origin and individual fractions thereof (entire reference especially paragraph 1 and 5 on p. 2, paragraph 3 on page 3, and claims on p. 18).

Regarding claims 1 and 9, Kurashov et al. do not teach the elements of isolating or transfecting genes.

Regarding claim 1 and 9, Carroll et al. teach the method comprising: isolating a starting microorganism capable of converting one material into another, such as amino acids into proteins;

isolating from the starting microorganism the genes responsible for the conversion ability by using an oligonucleotide probe complementary to a gene responsible for the conversion ability; and

Art Unit: 1637

placing the probe under hybridizing conditions in contact with amplicons from other microorganisms suspected or being capable of said conversion;

isolating amplicons which hybridized; and

transfecting the isolated amplicons into a host microorganism and determining whether productivity improved. (see entire article, especially Figure 4 which summarizes mehods of transfecting genetic material from a starting organism including a microorganism into a host microorganism, Figure 11 for probe amplification of the target gene, and see Introduction on p. 2495 the manufacture of large quantities of protein).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods of Kurashov et al. by using recombinant DNA technology as taught by Carroll et al. to produce hydrocarbons identical to those contained in petroleum of natural origin and individual fractions thereof with a reasonable expectation of success. The motivation to do so is provided by Carroll et al who teach: "The overall goal of recombinant-DNA technology is to identify, isolate, manipulate, and re-express genes from a given host (1-9). Some of the practical goals of such cut-and-paste technology is to 1) develop a basic understanding of the function and regulation of known gene products. 2) identify new genes whose protein products have not been isolated (reverse genetics). 3) correct endogenous genetic defects (eg. sickle cell anemia). 4) express foreign genes in disease-susceptible hosts (eg. Disease resistance genes in agricultural crops). and 5) manufacture large quantities of a protein product for widespread use" (see Introduction). Thus, the

claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

12. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choi et al. (1998) as applied to claim 11 above, and further in view of Wigler et al. (US Patent No. 5,436,142 issued 1995).

Choi et al. (1998) teach as noted above.

Choi et al. (1998) do not specifically teach subtractive hybridization and were this is performed by representational difference analysis.

Regarding claims 14 and 15, Wigler et al. teach isolation of genes by subtractive hybridization and were this is performed by representational difference analysis (entire reference, especially column 2 lines 28-41 and claims 1-14).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods of Choi et al. (1998) by using the subtractive hybridization method of representational difference analysis disclosed by Wigler et al. with a reasonable expectation of success. The motivation to do so is provided by Wigler et al. who teach that the subtractive hybridization method of representational difference analysis: "... permits the detection of sequences which differ between the two sources, where under selective conditions of hybridization, DNA from one of the two sources is not significantly hybridized to DNA from the other source" (see column 2 lines 28-34). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Art Unit: 1637

Conclusion

Page 18

13. Claims 1, 3, 9, and 11-16 are not free of the prior art.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 7:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples Examiner
Art Unit 1637
January 15, 2007

KENNETH R. HORLICK, PH.D PRIMARY EXAMINER

1/18/07